

Remarks

Applicants thank the Examiner for the indication of the allowablity of claims 6, 27, 34, 41, and 43.

Rejection of Claims 8, 15, and 21 Under 35 U.S.C. §112, first paragraph

Claims 8, 15, and 21 stand rejected under 35 U.S.C. §112, first paragraph as allegedly lacking enablement. Applicants respectfully traverse the rejection.

Claim 15 recites a specific binding protein that specifically binds an isolated and purified peptide comprising an amino acid sequence that consists essentially of Thr-Leu-Leu-Glu-Tyr-Arg-Met (SEQ ID NO:4), or a variant thereof, wherein the variant comprises an amino acid substitution at amino acid positions 3, 4, or both 3 and 4. Claim 8 is dependant on claim 15 and recites that at least one amino acid substitution is an amino acid with an aromatic ring.

Claim 21 recites a specific binding protein that specifically binds an isolated and purified peptide comprising an amino acid sequence that consists essentially of Gly-Met-Asn-Leu-Thr-Trp-Tyr-Arg-Glu-Ser-Lys (SEQ ID NO:5), or a variant thereof, wherein the variant comprises an amino acid substitution at amino acid position number 5, 6, or both 5 and 6.

The Office Action asserts that Applicants have not demonstrated that the variant peptides exist on IgE bound to B cells or on free IgE. The Office Action concludes that antibodies that bind to unknown variant peptides would have no use. The Examiner further asserts that the ability of an antibody resulting from immunization with a variant peptide to bind the original peptide is unpredictable in view of Coleman *et al.* and

Lederman *et al.* As such, the Office concludes that the resulting antibody would have no use.

The claims are drawn to specific binding proteins, *e.g.*, antibodies. The claimed specific binding proteins are useful for, *inter alia*, diminishing the production of IgE in a dog. *See, e.g.*, page 32, lines 3-11. The claims specify that the specific binding proteins specifically bind an isolated and purified peptide comprising an amino acid sequence that consists essentially of SEQ ID NO:4, SEQ ID NO:5, or specified variants thereof. That is, the claimed specific binding proteins bind SEQ ID NO:4, SEQ ID NO:5, or specific variants thereof. The specification teaches that variant polypeptide character is not substantially affected relative to the starting peptide (*e.g.*, SEQ ID NO:4 or SEQ ID NO:5). Variant polypeptide character is not substantially affected if the variations do not preclude specific binding of the variant peptide to a specific binding protein of the starting peptide. See specification, page 15, lines 10-17. That is, the claimed specific binding proteins specifically bind to BOTH the starting polypeptide (*e.g.*, SEQ ID NO:4) AND the variant polypeptides.

Therefore, a claimed specific binding protein that specifically binds a variant polypeptide will ALSO specifically bind to the starting polypeptide (*e.g.* SEQ ID NO:4 or SEQ ID NO:5). As such, the use of a specific binding protein that specifically binds to a variant of SEQ ID NO:4 or SEQ ID NO:5 is the same as for specific binding proteins that specifically bind to SEQ ID NO:4 or SEQ ID NO:5, that is, diminishing the production of IgE in a dog. The existence of the variant sequences on IgE bound to B cells is of no importance, the claimed specific binding proteins specifically bind to SEQ ID NO:4, SEQ ID NO:5 AND the specified variant sequences.

The Office also asserts that the claims stand rejected for reasons set forth in Paper No. 22 (Office Action mailed 5/21/2001) and Paper No. 16 (Office Action mailed 10/24/2000). Under 35 U. S. C. § 112, all that is required is that the specification describe the invention in such terms as to enable a person skilled in the art to make and use the invention. Thus, the specification must teach one skilled in the art how to make and use a specific binding protein that binds to an isolated and purified peptide comprising an amino acid sequence that consists essentially of SEQ ID NO:4 SEQ ID NO:5 or a variant thereof, wherein the variant comprises an amino acid substitution at amino acid positions 3, 4, or both 3 and 4 for SEQ ID NO:4 and at amino acid positions 5, 6, or both 5 and 6 for SEQ ID NO:5.

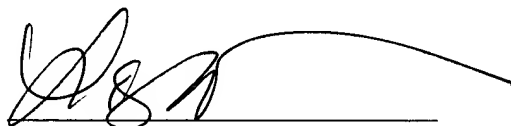
The test of enablement is whether one reasonably skilled in the art (1) could make and use the invention (2) from the disclosures in the patent coupled with information known in the art (3) without undue experimentation. *In re Wands*, 858 F.2d 731 (Fed. Cir. 1988); *United States v. Telectronics, Inc.*, 857 F.2d 778 (Fed. Cir. 1988); M.P.E.P. § 2164.01. “The determination of what constitutes undue experimentation is a given case requires the application of a standard of reasonableness, having due regard of the nature of the invention and the state of the art.” *In re Wands*, 8 U.S.P.Q.2d 1400, 1404 (Fed. Cir. 1988) (citing *Ansul Co. v. Uniroyal, Inc.*, 169 U.S.P.Q. 759, 762-63 (2d Cir. 1971). “The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed.” *Id.*

The specification clearly teaches that positions 3 and 4 of SEQ ID NO:4 and positions 5 and 6 of SEQ ID NO:5 can be any amino acid. The specification clearly teaches that substitutions can be made within a core sequence of SEQ ID NO:4 or SEQ ID NO:5. Specifically, the specification teaches that a core peptide sequence comprises Leu-Xaa-Xaa-Tyr-Arg (SEQ ID NO:1). See page 10, lines 16-23. Both SEQ ID NOs:4 and 5 comprise the core sequence of SEQ ID NO:1 and can therefore comprise substitutions between the core Leu residue and the Tyr-Arg pair. Applicants remind the Office that the Office must accept as being true the statements supporting enablement unless there is an objective reason, usually supported with documentary evidence to question them.

The specification also provides routine assays that can be used to determine if a claimed specific binding protein of the invention specifically binds a variant peptide. See Example 2.

Therefore, one of skill in the art could make and use the a specific binding protein that binds to a polypeptide shown in SEQ ID NO:4, SEQ ID NO:5, or the recited variants of SEQ ID NO:4 and SEQ ID NO:5. As such the claimed variants are enabled by the specification. Applicants respectfully request withdrawal of the rejection.

Respectfully submitted,



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